

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#6



Application of:

D. PAUL *et al.*

Application No.: To Be Assigned

Group Art Unit: 3732 (Expected)

Filed: HEREWITH

Examiner: Not Yet Assigned

For: INTERVERTEBRAL ALLOGRAFT Attorney Docket No.: 8932-295
SPACER

**PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102(d)
AND INCORPORATED INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

03/15/2002 11:00 AM Patent Application 01 FC:122 This is a petition to the Commissioner to make special the above-identified patent application. The grounds and conditions for granting this application special status are found in M.P.E.P. § 708.02 VIII entitled "Special Examining Procedure for Certain New Applications --Accelerated Examination".

In accordance with the requirements of 37 C.F.R. § 1.102(d) and 37 C.F.R. § 1.17, a Petition Fee of \$130.00 is believed to be due. Please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

As provided in M.P.E.P. § 708.02 VIII, Applicants agree to the special examining procedure detailed therein. In support of this Petition, Applicants provide the following:

- I. A statement that the claims are directed to a single invention.
- II. A description of the pre-examination searches performed in connection with this application.
- III. A copy of each of the documents identified by the pre-examination searches.

IV. A discussion of these documents pointing out, with the particularity required by 37 C.F.R. §§ 1.111(b) and 1.111(c), how the claimed subject matter is distinguishable over the documents.

I. The Claims Are Directed To a Single Invention

It is believed that Claims 1-20, which constitute all of the claims of the present application, are directed to a single invention, *i.e.*, an intervertebral implant and a method for restoring disc height between adjacent vertebrae. Claims 1 and 15 are the sole independent claims. If the United States Patent and Trademark Office ("USPTO") determines that all the pending claims are not directed to a single invention, Applicants submit that an election without traverse will be made.

II. Description of the Pre-examination Searches

The present application is a continuation-in-part of U.S. Patent Application No. 09/363,844, filed July 30, 1999 which claims the benefit under 35 U.S.C. § 119(e) of Provisional Application No. 60/095,209, filed August 3, 1998, and is a continuation of U.S. Patent Application No. 09/219,439, filed December 23, 1998, now U.S. Patent No. 6,143,033, which in turn claims the benefit under 35 U.S.C. § 119(e) of Provisional Application No. 60/073,271, filed on January 30, 1998 and Provisional Application No. 60/095,425, filed on August 5, 1998.

PCT Application No. PCT/EP99/00433 is an international application corresponding to the '844 application and PCT Application No. PCT/EP99/05541 is an international application corresponding to the '439 application. An International Search Report has been established for each PCT application, and a copy of each is enclosed herewith.

These PCT applications disclose and claim subject matter substantially similar to the claims of this application. The claims searched by the International Searching Authority, therefore, encompass the subject matter claimed in the instant application. Thus, the search is directly relevant to the subject matter claimed in the instant application. As M.P.E.P. § 708.02 VIII (c) explicitly provides, a search made by a foreign patent office

satisfies the requirement of a pre-examination search, Applicants submit, therefore, that this search fulfills the requirements of M.P.E.P. § 708.02 VIII (c).

Additionally, Applicants respectfully submit that the searches conducted by the USPTO in the course of prosecution of the '844 application and the '439 application qualify as sufficient pre-examination searches. These applications disclose and claim subject matter substantially similar to the claims of this application. The claims searched by the USPTO in the '844 and '439 applications, therefore, should encompass the subject matter claimed in the instant application. Thus, the searches performed in these prior applications are relevant to the subject matter claimed in the instant application and Applicants submit, therefore, that these searches fulfill the requirements of M.P.E.P. § 708.02 VIII (c).

Applicants' attorneys have also conducted pre-examination searches at the USPTO for references related to the claimed subject matter. The field of search included the following classes/subclasses:

Class 606 Subclasses 60, 61, 76, and 77

Class 623 Subclasses 16.11, 17.11, 17.15, 17.16, 23.63, 23.51, 23.50, 17.12, 17.13, 17.14, 23.63, 23.51, 23.50, 908, 919, and 925

The following classes/subclasses were searched by computer using only the following keywords: allograft, allogenic, allograph, natural, autologous, autograph, autogenic, xenogenic, xenograph, and bone.

Class 128 Subclass 898

Class 424 Subclasses 422, 423, 424, 425, 426, and 549

Class 523 Subclasses 113 and 115

Foreign patents available through the Internet addresses of the European Patent Office and the Japanese Patent Office were also review for international classes A61F2/28 and A61F2/44. The following keywords were used to review the references uncovered in these classes: allograft, allogenic, allograph, natural, autologous, autograph, autogenic, xenogenic, and xenograph.



III. Results of Pre-examination Searches

As discussed in more detail below, 265 references were uncovered as a result of the above-identified searches. Based on review of these references by Applicants' attorneys and in accordance with M.P.E.P. § 708.02 VIII (d), the following references are identified as most closely related to the subject matter encompassed by the claims:

U.S. Patent No. 6,200,347 (the "Anderson '347 patent")
U.S. Patent No. 5,989,289 (the "Coates '289 patent")
U.S. Patent No. 5,972,368 (the "McKay '368 patent")
U.S. Patent No. 5,888,227 (the "Cottle '227 patent")
U.S. Patent No. 5,728,159 (the "Stroeve '159 patent")
U.S. Patent No. 5,514,180 (the "Heggeness '180 patent")
PCT Publication No. WO 00/74608 (the "PCT '608 publication")
PCT Publication No. WO 99/09914 (the "PCT '914 publication")
PCT Publication No. WO 95/15133 (the "PCT '133 publication")

A copy of each reference is submitted herewith, along with a properly completed revised form PTO-1449, entitled "List of References Cited by Applicant".

IV. Discussion of the Documents Resulting from the Pre-examination Searches

This section provides a discussion of the above-listed documents. This discussion points out, with the particularity required by 37 C.F.R. §§ 1.111(b) and 1.111(c), how the claimed subject matter is distinguishable over the documents.

Applicants reserve the right to further establish the patentability of the claimed invention over any of the references described herein should they be applied as prior art references, and/or to prove that some of these references may not be prior art, and/or to prove that some of these references may not be enabling of the teachings they purport to offer.

Claims 1-14 recite an intervertebral implant comprising a plug of allogenic bone conforming in size and shape with a portion of the end plates of adjacent vertebrae and a method for using the implant. Claims 15-20 recite an implant for restoring disc height between adjacent vertebrae comprising an annular plug of allogenic bone surrounding an interior space. The top and bottom surfaces of the implant include a plurality of teeth

provided in at least a two dimensional array with the teeth being spaced apart from one another for interlocking with the adjacent vertebrae. The teeth have a pyramidal shape defined by four sides forming an acute angle with respect to the respective top and bottom surfaces of the implant. As now discussed in more detail, none of the cited references discloses or teaches this invention.

A. Anderson '347 Patent

The Anderson '347 patent is directed to a composite bone graft that has one or more textured surfaces with a plurality of continuous protrusions or grooves. These grooves extend across substantially the entire surface. Thus, the Anderson '347 patent does not show, suggest, or teach an allogenic plug wherein the top and bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

B. Coates '289 Patent

The Coates '289 patent is directed to an allogenic spacer. The majority of the disclosed embodiments have grooves, not teeth, and these grooves extend across substantially the entire superior and inferior faces. While the Coates '289 patent does illustrate the use of teeth in one embodiment, other than what is shown in Figure 12, *Coates is absolutely silent concerning the geometry, shape, or arrangement of the teeth*. This silence is in stark contrast to the extensive discussion of the shape and location of the grooves. Figure 12 of the Coates '289 patent shows a single row of teeth formed in two ridges, each ridge located on the top face on opposite sides of and along the perimeter of the implant. The Coates '289 patent does not show, suggest, or teach an allogenic plug wherein the top and bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

C. McKay '368 Patent

The McKay '368 patent is directed to bone composites and spacers and discloses a cortical ring that includes teeth. As shown in Figure 8, the teeth are spaced as a ring along the perimeter and appear to have a conical shape. Other than what is shown in Figure 8, *McKay is absolutely silent concerning the geometry or shape of the teeth*. The McKay '368 patent does not show, suggest, or teach an allogenic plug wherein the top and

bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

D. Cottle '227 Patent

The Cottle '227 patent discloses an inter-vertebral implant having a frame-like cage 1 with cover and base faces 11, 12 that have a three dimensional structure 18. Cottle discloses that the implant can be made of titanium, titanium alloy, ceramic, or a biocompatible plastic. The Cottle '227 patent does not show, suggest, or teach an allogenic plug wherein the top and bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

E. Stroever '159 Patent

Stroever teaches a serrated bone graft with the serrations substantially similar to the grooves of the Coates '289 patent. The Stroever '159 patent does not show, suggest, or teach an allogenic plug wherein the top and bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

F. Heggeness '180 Patent

The Heggeness '180 patent discloses prosthetic intervertebral devices. The Heggeness '180 patent does not show, suggest, or teach an allogenic plug wherein the top and bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

G. PCT '608 Publication

The PCT '608 publication discloses a ramp-shaped intervertebral implant formed from bone, bone composites, or any biocompatible material. The implant has an opening that extends through upper and lower surfaces and a series of ridges on at least one of the upper and lower surfaces. These ridges extend substantially across the entire surface. Thus, the PCT '608 Publication does not show, suggest, or teach an allogenic plug wherein the top and bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

H. The PCT '914 Publication

The PCT '914 publication is directed to an allogenic spacer. All embodiments have grooves, not teeth. The PCT '914 publication does not show, suggest, or teach an allogenic plug wherein the top and bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

I. PCT '133 Publication

The PCT '133 publication discloses a spinal disk implant that has teeth and is made of a ceramic, metal, polymer, or composite material. The PCT '133 publication does not show, suggest, or teach an allogenic plug wherein the top and bottom surfaces have a plurality of pyramidal shaped teeth provided in at least a two dimensional array.

VI. Information Disclosure Statement

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the USPTO of all references coming to the attention of Applicants or attorneys or agents for Applicants which are or may be material to the patentability of any claim of the subject application, attorneys for Applicants hereby direct the Examiner's attention to the references listed on the attached revised Form PTO-1449. Copies of all references listed thereon in reverse chronological order are submitted herewith.

The references listed on the revised Form PTO-1449 include each of the references discussed above, *i.e.* those references considered by the Applicants to be most closely related to the subject matter encompassed by the claims, as well as references Applicants believe to be less material than the references discussed herein.

Identification of the references listed on the revised Form PTO-1449 is not to be construed as an admission by Applicants or attorneys for Applicants that such references are available as "prior art" against the subject application. Further, Applicants believe that the presently claimed invention is patentable over the each of the cited references.

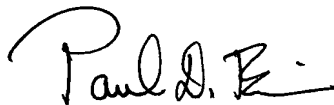
VII. Conclusion

Applicants respectfully submit that the requirements of 37 C.F.R. § 1.102 and M.P.E.P. § 708.02 pertaining to special status have been satisfied. Accordingly, it is respectfully requested that this Petition be granted.

This statement should not be construed as a representation that an exhaustive search has been made, or that there does not exist information more material to the examination of the present patent application. The submission of this material is **not** intended to displace the Examiner's professional ability and duty to search. Indeed, the Examiner is specifically requested **not** to rely solely on the materials submitted herewith. The Examiner is requested to conduct an independent and thorough review of the documents, and to form independent opinions as to their significance.

Respectfully submitted,

Date April 9, 2001



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